Patency and Clinical Outcomes of a Dedicated, Self-Expanding, Hybrid Oblique Stent Used in the Treatment of Common Iliac Vein Compression

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Abstract: PURPOSE To investigate the clinical outcomes of a dedicated hybrid oblique nitinol stent that has been specifically designed to treat common iliac vein compression. METHODS The Bern Venous Stent Registry database was interrogated to identify all patients who had at least 6-month follow-up after treatment with the sinus-Obliquus hybrid stent for common iliac vein compression. The search identified 24 patients (mean age 39±18 years; 20 women) who matched the search criteria. Ten patients had postthrombotic syndrome (PTS), another 10 patients had acute iliofemoral thrombosis after catheter-directed therapy, and 4 patients had nonthrombotic iliac vein compression. Primary treatment success was defined as antegrade flow and stenosis <30% on venography and evidence of a spontaneous Doppler signal in the treated segment. Stent patency was assessed using duplex ultrasound. Clinical outcomes were evaluated using a clinical symptom score (Villalta) and the revised venous clinical severity score (rVCSS) at 3, 6, and 12 months in follow-up. RESULTS Primary treatment success was achieved in all patients. Mean follow-up was 10±3 months. Primary patency estimates by Kaplan-Meier analysis were 92% at 6 months [95% confidence interval (CI) 71% to 98%] and 83% (95% CI 54% to 95%) at 10 months. Three symptomatic patients underwent reintervention for early and late stent thromboses and the third for in-stent restenosis, resulting in secondary patency of 100%. Overall, all patients had clinical improvement at the latest follow-up; 50% reported complete resolution of symptoms. In patients with PTS, the Villalta score decreased by 6±6 points (p=0.02) and the rVCSS score by 3±1 points (p=0.05). Among deep vein thrombosis patients, none developed PTS. CONCLUSION In patients with common iliac vein compression, the oblique hybrid nitinol stent appears to provide excellent early patency and clinical outcomes.

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Anna K. Stuck, MD[1], Samuel Kunz[2], Iris Baumgartner, MD[1], and Nils Kucher, MD[1]

Abstract

Purpose: To investigate the clinical outcomes of a dedicated hybrid oblique nitinol stent that has been specifically designed to treat common iliac vein compression. **Methods:** The Bern Venous Stent Registry database was interrogated to identify all patients who had at least 6-month follow-up after treatment with the sinus-Obliquus hybrid stent for common iliac vein compression. The search identified 24 patients (mean age 39±18 years; 20 women) who matched the search criteria. Ten patients had postthrombotic syndrome (PTS), another 10 patients had acute iliofemoral thrombosis after catheter-directed therapy, and 4 patients had nonthrombotic iliac vein compression. Primary treatment success was defined as antegrade flow and stenosis <30% on venography and evidence of a spontaneous Doppler signal in the treated segment. Stent patency was assessed using duplex ultrasound. Clinical outcomes were evaluated using a clinical symptom score (Villalta) and the revised venous clinical severity score (rVCSS) at 3, 6, and 12 months in follow-up. **Results:** Primary treatment success was achieved in all patients. Mean follow-up was 10±3 months. Primary patency estimates by Kaplan-Meier analysis were 92% at 6 months [95% confidence interval (CI) 71% to 98%] and 83% (95% CI 54% to 95%) at 10 months. Three symptomatic patients underwent reintervention for early and late stent thromboses and the third for in-stent restenosis, resulting in secondary patency of 100%. Overall, all patients had clinical improvement at the latest follow-up; 50% reported complete resolution of symptoms. In patients with PTS, the Villalta score decreased by 6±6 points (p=0.02) and the rVCSS score by 3±1 points (p=0.05). Among deep vein thrombosis patients, none developed PTS. **Conclusion:** In patients with common iliac vein compression, the oblique hybrid nitinol stent appears to provide excellent early patency and clinical outcomes.

Keywords

compression, deep vein thrombosis, hybrid oblique stent, iliac vein, inferior vena cava, nitinol stent, postthrombotic syndrome, reintervention, thrombolysis, thrombosis

Introduction

The postthrombotic syndrome (PTS) is a common long-term complication of deep vein thrombosis (DVT), with an incidence rate up to 40%.[1,2] Patients with PTS suffer from leg swelling, venous claudication, or venous ulcers that impair the quality of life.[3,4] Of note, the risk of PTS is greatest in patients with proximal thrombosis involving the iliofemoral veins or the inferior vena cava (IVC).[1,4,5]

Conservative management of acute iliofemoral DVT with anticoagulation therapy and compression stockings is associated with poor venous patency rates.[6–8] Thus, early revascularization strategies now aim to restore venous flow, thereby preventing the development of PTS.[6,9] Catheter-directed thrombolysis followed by venous stenting has emerged as a promising revascularization strategy, with venous patency rates of 70% to 90% and low complication rates.[10–20]

The majority of iliofemoral DVTs are caused by iliac vein compression. The May-Thurner syndrome is an anatomical variant in a quarter of the population that results in compression of the left common iliac vein (CIV) against the fifth lumbar vertebra by the right iliac artery.[21,22] Treatment of venous thrombosis is particularly challenging in these anatomically compressed large veins. Atypical iliac vein compression can occur in both the left and right CIVs from ectatic or tortuous iliac arteries, anomalies of the vertebrae

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or sacrum, or osteosynthetic material used during spine surgery.

Focal external compression and the vicinity to the iliocaval bifurcation hamper venous stenting using conventional stents. An ideal venous stent for treating iliac vein compression comprises sufficient radial force at the compression site and flexibility to accommodate the anatomy of the curved iliac vein. The exact long-term rate of contralateral iliac vein thrombosis after conventional left iliac vein stenting is unknown. In a recent study of 51 patients with left CIV compression, the rate of contralateral iliac vein thrombosis after stenting of the left CIV with conventional non-oblique stent with its tip positioned 1.5 cm inside the IVC was 4% at a mean follow-up of 16 months.[23]

This study investigated venous patency rates and clinical outcomes of patients with CIV compression treated with a venous hybrid nitinol stent (sinus-Obliquus; Optimed, Ettlingen, Germany) that has a novel oblique proximal end.[24]

Methods

Study Design

Data were derived from the Bern Venous Stent Registry, an ongoing study that has been enrolling all patients who receive venous stents at the University Clinic of Angiology in Bern, Switzerland, since January 1, 2008. Indications for stenting of the iliofemoral veins and/or IVC are: (1) residual thrombosis after catheter-directed or pharmacomechanical thrombolysis; (2) PTS and chronic obstruction; or (3) chronic venous insufficiency with nonthrombotic stenosis. Exclusion criteria for registry enrollment are inability to provide informed consent, age below 18 years, or estimated life expectancy <3 months.

For all enrolled patients, baseline demographic information (age, gender, weight, height, stent type, indication); comorbid conditions (history of major bleeding, cardiovascular comorbidity, diabetes mellitus, renal impairment); risk factors (tobacco use, hormonal therapy, immobility); laboratory findings (creatinine, hemoglobin); and anticoagulant and antiplatelet therapy were recorded. Procedure data included the number and type of implanted stents, devices for pharmacomechanical or catheter-directed thrombolysis, and dosage of recombinant tissue plasminogen activator (r-tPA). The registry and participant consent form were approved by the Swiss Ethics Committee on research involving humans. The study is registered on the National Institutes of Health website (*ClinicalTrials.gov*; identifier NCT02433054).

For this analysis, the registry database was interrogated to identify patients who received a sinus-Obliquus stent after Conformité Européenne approval in December 2014 and had at least 6-month follow-up as of June 2016. Patients who were pregnant, breast-feeding, or had a postpartum period <30 days were excluded. The search identified 24 patients (mean age 39±18 years; 20 women) who matched the search criteria and were enrolled between December 2014 and November 2015. The baseline patient characteristics are given in Table 1. The indication for stent implantation was acute iliofemoral DVT in 10 patients, PTS in 10 patients, and nonthrombotic CIV compression in 4 patients. Overall, 4 patients presented with a recurrent venous thromboembolism (VTE).

Study Device

The sinus-Obliquus stent (Figure 1) features a proximal closed-cell section that provides high radial force at the compression site; the oblique design (35°) at the proximal end prevents jailing of the contralateral iliac vein. The open-cell distal segment affords flexibility and less radial force to better accommodate the curved anatomy of iliac veins during hip flexion.

Procedures

In acute patients, DVT was objectively confirmed by duplex ultrasound or contrast-enhanced computed tomography. Treatment of DVT, for example, anticoagulation therapy and thrombolysis, was at the discretion of the treating physician. In general, patients with acute DVT were treated initially with intravenous unfractionated heparin, adjusted to target an activated partial thromboplastin time corresponding to therapeutic heparin levels (equivalent to 0.3 to 0.7 U/mL by factor Xa inhibition). Catheter-directed therapy included pharmacomechanical thrombolysis if the DVT was confined to the iliac vein or ultrasound-assisted thrombolysis if the DVT extended to the femoral veins.

Pharmacomechanical thrombolysis was performed in a single session with the AngioJet system (DVX 6-F catheter; Boston Scientific, Marlborough, MA, USA) and intraclot injection of 10 mg of r-tPA using the high-pressure PowerPulse technique. Ultrasound-assisted thrombolysis was performed with the EKOS system (EKOS Corporation, Bothell, WA, USA),[25,26] infusing a total 20 mg r-tPA over 15 hours, with hemodynamic monitoring in the intermediate care unit. Following catheter-directed therapy, vitamin K antagonists were started or unfractionated heparin was switched to direct oral anticoagulants.

Prior to stent placement, a bilateral anteroposterior venogram was routinely performed via a crossover diagnostic catheter and the ipsilateral sheath to visualize the exact location of the iliac vein confluence, the distal IVC, and the iliac vein compression. Intravascular ultrasound was performed only if the extent and location of the CIV compression could not be visualized by bilateral venography.

The stent was advanced with its tip into the distal IVC. Correct positioning of the stent was achieved by (1) rotating

Table 1. Baseline Characteristics.[a]

Characteristic	Overall (n=24)	PTS (n=10)	Acute Thrombosis (n=10)	Iliac Vein Compression (n=4)
Age, y	39±18	36±12	37±23	47±18
Women	20	9	8	3
May-Thurner syndrome	20	8	9	3
Peripheral artery disease	1	0	1	0
Cerebrovascular disease	1	0	1	0
Liver insufficiency[b]	1	0	1	0
Hypertension	1	0	1	0
Diabetes	3	1	2	0
Smoking	10	3	5	2
Obesity	1	1	0	0
Previous VTE	4	3	1	0
Postpartum status[c]	1	1	0	0
Hormonal therapy[d]	7	1	5	1
Surgery and/or trauma[e]	2	2	0	0
Immobilization[f]	6	3	3	0
Known thrombophilia	4	3	1	0
Previous anticoagulation	16	10	6	0
Concomitant pulmonary embolism[g]	2		2	

Abbreviations: PTS, postthrombotic syndrome; VTE, venous thromboembolism.
[a]Continuous data are presented as the means ± standard deviation; categorical data are given as the counts.
[b]Liver insufficiency defined as ASAT/ALAT (aspartate aminitransferase / alanine aminotransferase) >100.
[c]Delivery within the previous 6 weeks.
[d]Defined as contraception, tamoxifen, or substitute.
[e]Within the previous month.
[f]Within the previous 3 months.
[g]Both low-risk pulmonary embolism.

the delivery system to align the 2 middle radiopaque markers and (2) by pulling back the stent system so that the lateral marker on the short end of the oblique section was placed ~5 mm into the IVC adjacent to the iliac vein confluence (Figure 2). Deployment of the stent was performed using a contrast overlay from the bilateral contrast injection to facilitate exact stent placement without compromising the contralateral IVC wall and without jailing the contralateral iliac vein. If the initial deployment of the closed-cell section was suboptimal, the stent was retrieved into the delivery catheter and a new deployment initiated. Additional stent extensions (sinus XL Flex; Optimed) were added as needed for long segment treatment.

Follow-up

Clinical follow-up assessments were performed at the vascular outpatient clinic by vascular specialists at baseline and at 3, 6, and 12 months in follow-up. At each visit, signs and symptoms of PTS were systematically calculated using the Villalta score as standard procedure for all patients with venous stents. A score <5 points indicated no PTS. Mild PTS was defined between 5 to 9 points, moderate between 10 and 14, and >15 points was considered severe PTS.[2,3] Moreover, the severity of the symptoms was assessed using the revised venous clinical severity score (rVCSS).[3,27] An additional score suggested by Bozkaya et al[11] was used to assess subjective development of symptoms by the patients themselves after intervention. Patients were categorized into the following 3 groups: clinical improvement (complete or partial) and symptoms unaffected compared to before intervention.

Duplex sonography was performed immediately after stent implantation and at 3, 6, and 12 months. Each stented venous segment was examined for (1) the presence or absence of thrombotic changes (thickening of the venous wall, intraluminal webs, intraluminal material); (2) the presence of reflux (>0.5 seconds during Valsalva maneuver or distal compression) in nonoccluded segments below the groin; and (3) flow patterns in treated segments to determine if they were modulated by the cardiac cycle, spontaneously modulated with respiration, or modulated with deep inspiration. Flow velocities were recorded.

Definition of Outcomes

Primary treatment success was defined as antegrade flow and maximal luminal stenosis of 30% after intervention examined with venography and evidence of a spontaneous Doppler signal in the treated vein segment.[10,11,13,28] Primary

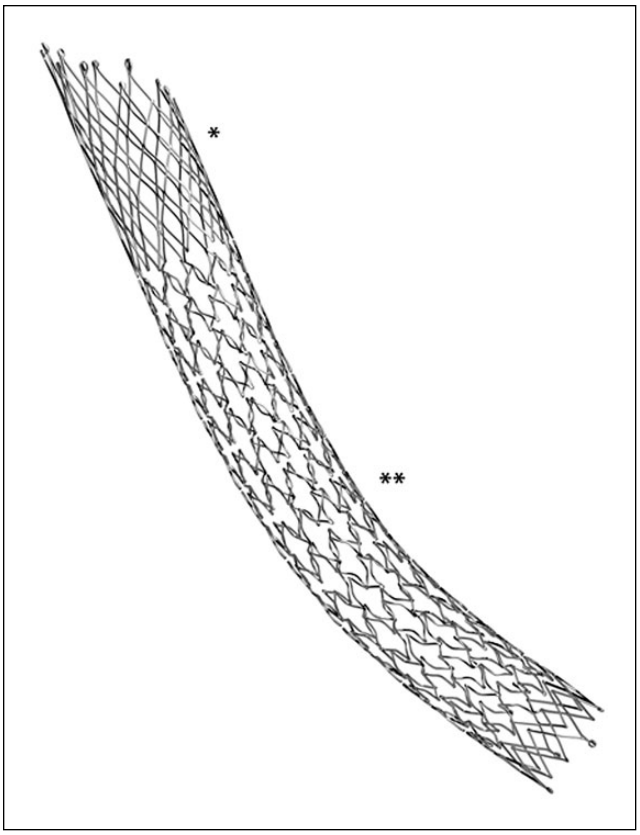

Figure 1. Photograph of the sinus-Obliquus stent (courtesy of Optimed). *The proximal section of the stent provides high radial force at the site of common iliac vein compression, enabled by a closed-cell design. The proximal tip of the stent has an oblique (35°) design to protect the contralateral iliac vein inflow. The proximal tip of the stent contains 4 radiopaque markers for correct positioning of the stent (see Figure 2). **Owing to its open-cell design, the distal segment of the stent provides high flexibility and less radial force to accommodate the curved anatomy of the iliac veins during hip flexion.

patency referred to primary treatment success without either thrombosis of the treated segment or reintervention. Secondary patency primary was treatment success without permanent loss of flow in the treated segment irrespective of any interval therapies. Primary sustained clinical success was defined as the absence of PTS (Villalta score 0–4 points) without the need for repeated intervention assessed at the latest follow-up visit.

Restenosis in the treated venous segment was defined by ultrasound as a luminal obstruction >50% of the venous cross-sectional area in B-mode or deterioration of the Doppler flow pattern from the first postinterventional day to the follow-up ultrasound study, including an increase of antegrade blood flow velocity to >1 m/s or absent respiratory modulation of flow at follow-up if respiratory modulation was present 1 day after stent placement. Restenosis occurring in the first 30 days was defined as early onset.

Statistical Analyses

Data were presented as means ± standard deviations or absolute numbers for continuous and categorical variables, respectively. Categorical data were analyzed using the chi-square test. Means were compared using a 2-sided paired Student *t* test. Kaplan-Meier survival analysis was used to estimate patency rates, which are reported with the 95% confidence interval (CI). A $p<0.05$ indicated statistical significance. All statistical analyses were performed using STATA statistical software (version 13.0; StataCorp LP, College Station, TX, USA).

Results

Mean time between the most recent DVT and intervention was 7±14 days in patients with acute DVT and 10±14 years in patients with PTS. Ultrasound-assisted thrombolysis was performed in 9 patients and pharmacomechanical thrombolysis in 1. Among the 10 patients with DVT, complete thrombolysis success was achieved in 7; 3 patients had >50% of thrombus removed. One acute DVT patient suffered a retroperitoneal hematoma after ultrasound-assisted thrombolysis, requiring surgical evacuation.

With the exception of 1 patient, all sinus-Obliquus stents were implanted in the left CIV. Twelve patients received 1 stent only and 12 patients received a distal stent extension with a second or third stent. Diameters of the sinus-Obliquus stents were 14 mm in 16 patients and 16 mm in 8; stent lengths ranged from 80 to 150 mm. Primary treatment success was achieved in all 24 patients.

Overall, 17 patients were treated with rivaroxaban (15 mg twice daily for 3 weeks followed by 20 mg/d) and 6 received low-molecular-weight heparin as a bridge to vitamin K antagonist for the initial 3 months postintervention. Anticoagulation therapy was stopped at 3 months in 1 patient with acute DVT and after 6 months in 3 patients (2 with acute DVT and 1 with PTS). The other patients had ongoing anticoagulation therapy.

Follow-up

Mean follow-up was 10±3 months (range 6–18). The primary patency rate was 92% (95% CI 71% to 98%) at 6 months and 83% (95% CI 54% to 95%) at 10 months (Figure 3). Two patients had minor bleeding during follow-up (1 patient had mild popliteal hematoma at the puncture site and 1 patient had hypermenorrhea).

Three patients had symptomatic stent thrombosis (1 early and 1 late) or in-stent restenosis. The patient with early stent thrombosis had a stent extension below the inguinal ligament during the index intervention. The patient with late stent thrombosis had recurrent VTE (low-risk pulmonary embolism) occurring concomitantly at the time of

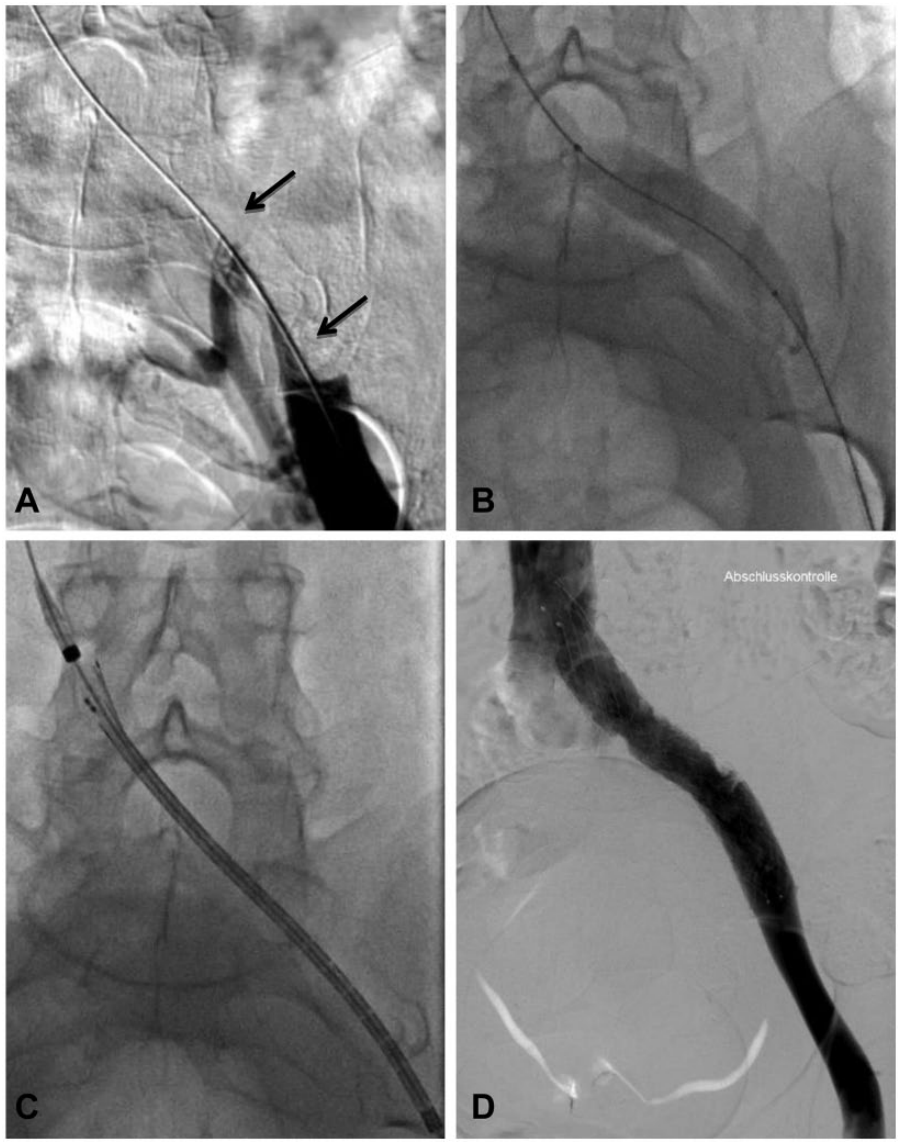

Figure 2. Digital subtraction venograms from a patient with acute iliofemoral thrombosis. (A) After catheter-directed thrombolysis, thrombosis in the external iliac vein is resolved; note the stenosis of the left common iliac vein (typical May-Thurner compression, arrows). (B) Balloon angioplasty for predilation of the left common iliac vein using a 14-mm high-pressure balloon catheter. (C) Radiograph showing the initial deployment phase of the closed-cell segment of the sinus-Obliquus stent (14×100 mm) at the origin of the left common iliac vein. (D) Final venogram of the postdilated sinus-Obliquus stent in the left common and external iliac veins. Note that the proximal segment of the stent does not reach the contralateral wall of the inferior vena cava and that the short end of the oblique segment was placed ~5 mm inside the inferior vena cava adjacent to the iliac vein confluence.

stent occlusion. All 3 patients had successful recanalization (secondary patency 100%).

The patient with early stent thrombosis underwent successful ultrasound-assisted thrombolysis and distal stent extension into the deep femoral vein; at the time of stent thrombosis, this patient was not on therapeutic anticoagulation. The patient with late stent thrombosis was on therapeutic anticoagulation with a vitamin K antagonist; he had pharmacomechanical thrombolysis with stent-in-stent placement in the CIV. The patient with symptomatic in-stent restenosis required distal stent extension into the deep femoral vein after 4 months. One patient had asymptomatic in-stent obstruction <50% by ultrasound and was treated conservatively. There were no cases of symptomatic stent

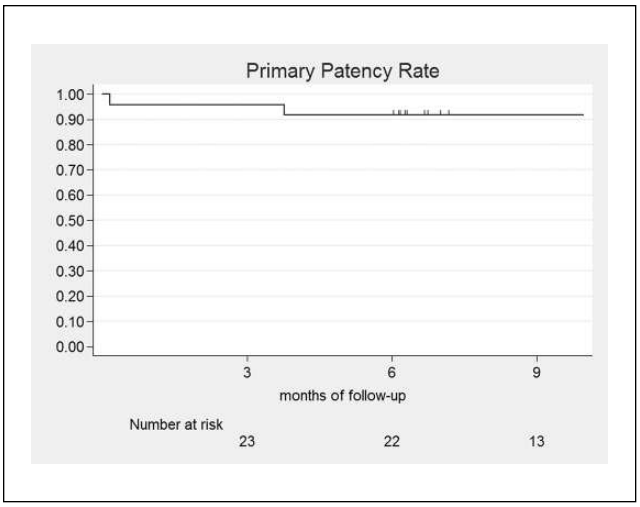

Figure 3. Kaplan-Meier estimates of the primary patency rates for 24 patients treated with the sinus-Obliquus stent. The standard error is 6% at 10 months.

compression or contralateral iliac vein thrombosis during follow-up.

According to the Bozkaya score,[11] all patients had subjective clinical improvement at the latest follow-up; 50% reported complete resolution of symptoms. In patients with acute DVT, all patients were free from the PTS at the latest follow-up (6 patients had 0 points, 2 patients had 1 point, and 2 patients had 3 points). In PTS patients, the mean Villalta score was 10±3 at baseline and 4±2 at latest follow-up, resulting in a statistically significant mean reduction in the Villalta score of 6±6 points (p=0.02). The mean rVCSS decreased by 3±1 points (baseline 5.0±3.9 points; p=0.05). At the latest follow-up, 6 of 10 PTS patients had a Villalta score <4, classifying them as free from PTS after intervention.

Discussion

The sinus-Obliquus stent was designed to accommodate the specific needs for treatment of CIV compression. The hybrid design with proximal closed-cell and distal open-cell segments was chosen to provide maximum radial force at the compression site and maximum flexibility in the non-compressed curved iliac veins. The oblique end of the closed-cell section was designed for precise placement at the origin of the iliocaval bifurcation without the need to place the stent too far into the IVC, thereby reducing the risk of jailing the contralateral CIV.

Overall, our findings are consistent with prior studies of other venous stents, with good patency, few complications, and no mortality.[16] A number of dedicated venous stents have been investigated, for example, the Vici (VENITI Inc, St Louis, MO, USA), Zilver Vena (Cook, Bloomington, IN, USA), and the sinus-Venous (Optimed). O'Sullivan et al[29] reported a short-term patency rate of 85% for the Zilver Vena stent in patients with acute DVT and malignant venous obstructions. Another study investigating the sinus-Venous stent in PTS patients reported a patency rate of 99% at 3 months and 92% at 12 months, resulting in an improvement in PTS as reflected by a significant decrease in the VCSS and Villalta scores.[18]

In this study, no differences were found in terms of patency rates between thrombotic and nonthrombotic disease. In contrast, prior evidence suggests that outcomes may differ. Recent studies demonstrated that primary patency rates were lower for patients with PTS compared to patients with nonthrombotic iliac vein stenosis.[18,30,31] A possible explanation suggested by the authors might be that the compromised venous inflow from the femoral veins due to postthrombotic lesions may result in higher reocclusion rates. Accordingly, our PTS patients were treated with an aggressive strategy that called for distal stent extension to achieve optimal inflow. In patients with iliac vein stenting after catheter-directed thrombolysis, our results are similar to others,[23] with excellent patency up to 1 year.

Limitations

This study was limited by the small study population and short follow-up. The exact rate of asymptomatic stent compression/restenosis could not be determined because ultrasound surveillance may have missed it in patients with poor-quality ultrasound images of the iliac veins. However, it is unlikely that severe asymptomatic forms were missed if the Doppler signal in the common femoral vein remained unchanged from the day of intervention to follow-up. Also, asymptomatic stent fractures could not be identified because routine radiographic examinations were not performed during follow-up. However, it is unlikely that stent fractures leading to severe asymptomatic restenosis were missed.

Moreover, our population treated with sinus-Obliquus stents mainly consisted of young, healthy female patients. If treatment with sinus-Obliquus stents becomes a broadly accepted therapy, venous stenting has to be studied in multimorbid and elderly patients as well. However, the originality of our study lies in the fact that acute thrombotic, postthrombotic, and nonthrombotic iliac vein compression syndromes were investigated.

Conclusion

Short-term patency and clinical outcomes in patients with CIV compression treated with the sinus-Obliquus stent were excellent. Further studies need to investigate the

efficacy and safety of sinus-Obliquus stenting in a long-term perspective.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Prof Nils Kucher received consultant honoraria from Optimed, Germany.

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